has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 44450, Dec. 10, 1986, as amended at 61 FR 29480, June 11, 1996; 62 FR 4164, Jan. 29, 1997]

§ 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.745 of this chapter.

(d) *Conditions of use*—(1) *Beef and nonlactating dairy cattle*—(i) *Amount.* 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis.* For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis.* For the treatment of infectious bovine keratoconjunctivitis associated with *Moraxella bovis.* For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii.*

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 2.5 mg/kg body weight as a single intramuscular injection in the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, and *M. hyopneumoniae* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 5 days from the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 39918, July 12, 2005, as amended at 71 FR 57416, Sept. 29, 2006; 72 FR 54540, Sept. 26, 2007; 73 FR 6018, Feb. 1, 2008; 73 FR 58872, Oct. 8, 2008; 74 FR 53165, Oct. 16, 2009]

§ 522.2640 Tylosin.

(a) *Specifications.* Each milliliter of sterile solution of 50 percent propylene glycol with 4 percent benzyl alcohol contains 50 to 200 milligrams of tylosin activity (as tylosin base). Tylosin conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography," which is incorporated by reference. Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) *Sponsors.* (1) See No. 000986 in § 510.600(c) of this chapter for use in paragraphs (e)(1), (2), and (3) of this section.

(2) See No. 000010 in § 510.600(c) of this chapter for use as in paragraphs (e)(1) and (2) of this section.

(c) [Reserved]

(d) *Related tolerances.* See § 556.740 of this chapter.

(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i)